FORM PTO-149
(REV. 7-98)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:
200.1102CIP

SERIAL NO.: 09/503,020

LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): Robert F. KAIKO, Robert D. COLUCCI

FILING DATE: February 11,
2000

GROUP: 1615

U.S. PATENT DOCUMENTS

*EXAMINE R INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
<i>TS</i>	AA	5	6	1	6	6	0	1	4/1/97	Khanna et al.	514	399	6/5/95
	AB	5	7	6	7	1	2	5	6/16/98	Crain et al.	514	282	12/3/96
	AC	5	6	2	4	9	3	2	4/29/97	Qin et al.	514	282	6/7/95
<i>TW</i>	AD	5	5	8	5	3	4	8	12/17/96	Crain et al.	514	12	8/13/93
	AE												
	AF												
	AG												
	AH												
	AI												
	AJ												
	AK												

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
<i>TW</i>	AL	0	9	1	3	1	5	2	6/5/99	EP(A1)	A61K	31/485	abstract	
	AM	4	3	2	5	4	6	5	2/2/95	DE(A)	A61K	31/485	abstract	
	AN	0	3	5	2	3	6	1	1/31/90	EP(A1)	A61K	31/485		
	AO	19	6	5	1	5	5	1	6/18/98	DE(A1)	A61K	31/485	abstract	
<i>TW</i>	AP	WO	98	3	5	6	7	9	8/20/98	<i>PCT W/T</i>	A61K	31/485, 47/02, 47/06	abstract	

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

<i>TS</i>	AR	Gan et al., "Opioid-sparing Effects of a Low-dose Infusion of Naloxone in Patient-administered Morphine Sulfate.", Anesthesiology, Vol. 87(5), (1997) pp. 1075-1080.
	AS	
	AT	

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Todd B. Bels

DATE CONSIDERED

4-29-03

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Sheet 2 of 9

FORM PT 3449

(REVISED 10/98)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:
200.1102US

SERIAL NO.: 09/218,662

LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): Robert F. KAIKO, Robert D. COLUCCI

FILING DATE: December 22,
1998

GROUP: 1615

U.S. PATENT DOCUMENTS

*EXAMINE R INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	BA						
	BB						
	BC						
	BD						
	BE						
	BF						
	BG						
	BH						
	BI						
	BJ						
	BK						

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FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
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<i>TW</i>	BL	WO 97 3 3 5 6 6	9/18/97	PCT W/PV	A61K	9/20		
<i>I</i>	BM	WO 83 0 3 1 9 7	9/29/83	PCT W/PV	A61K	9/22, 31/485		
	BN	29 7 1 9 7 0 4	2/14/97	DE	A61K	31/485	claims	
<i>TW</i>	BO	WO 96 0 2 2 5 1	2/1/96	PCT W/PV	A61K	31/485		
	BP							

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	BR	
	BS	
	BT	

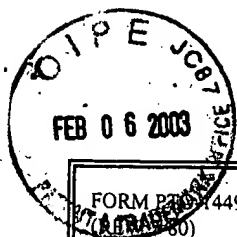
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Michael P. Ward

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4-29-03

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FORM PTO 449
(A-TR-80)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:
200.1102CIP

SERIAL NO.: 09/503,020

LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): Robert F. KAIKO, Robert D. COLUCCI

FILING DATE: February 11,
2000

GROUP: 1615

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
<i>TW</i>	CA	2	7	7	0	5	6	9	11/13/56	Fromherz, et. al.	167	65	10/15/52
	CB	3	4	9	3	6	5	7	2/3/70	Lewenstein, et. al.	424	260	1/23/64
	CC	3	6	7	6	5	5	7	7/11/72	Lachman, et. al.	424	260	3/2/71
	CD	3	7	7	3	9	5	5	11/20/73	Pachter, et. al.	424	260	8/3/70
	CE	3	8	7	9	5	5	5	4/22/75	Pachter, et. al.	424	260	8/16/73
	CF	3	9	6	6	9	4	0	6/29/76	Pachter, et. al.	424	260	9/2/75
	CG	4	4	5	7	9	3	3	7/3/84	Gordon, et. al.	424	260	12/11/81
	CH	4	4	0	1	6	7	2	8/30/83	Portoghese	424	260	10/13/81
	CI	4	4	6	4	3	7	8	8/7/84	Hussain, et. al.	424	260	4/28/81
	CJ	4	5	7	3	9	9	5	3/4/86	Chen, et. al.	604	896	10/9/84
<i>TW</i>	CK	4	5	8	2	8	3	5	4/15/86	Lewis, et. al.	514	282	12/5/84

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
<i>TW</i>	CL	2	2	2	2	0	3	9	11/23/72	DE	A61K	27/00	Abstract	
<i>TW</i>	CM	WO	94	0	6	4	2	6	3/31/94	PCT (AI) <i>WPU</i>	A61K	31/46		
<i>TW</i>	CN	WO	95	0	3	8	0	4	2/9/95	PCT (AI) <i>WPU</i>	A61K	31/485		
	CO													
	CP													

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

<i>TW</i>	CR	Sunshine, et. al., "Analgesic Efficacy of Pentazocine Versus a Pentazocine-Naloxone Combination Following Oral Administration", Clin. J. Pain 1988; 4:35-40.
<i>TW</i>	CS	Wang, et. al., "Crossover and Parallel Study of Oral Analgesics", J. Clin. Pharmacol 1981; 21:162-8
<i>TW</i>	CT	Gonzalez JP, et. al., Naltrexone: A review of its Pharmacodynamic and Pharmacokinetic Properties and Therapeutic Efficacy in the Management of Opioid Dependence. Drugs 1988; 35:192-213.

EXAMINER

Robert D. Colucci

DATE CONSIDERED

4-29-03

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Sheet 4 of 9

FORM PTO-1449
(Rev. 7-80)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:
200.1102CIP

SERIAL NO.: 09/503,020

LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): Robert F. KAIKO, Robert D. COLUCCI

FILING DATE: February 11,
2000

GROUP: 1615

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
<i>DR</i>	DA	4	6	0	8	3	7	6	8/26/86	Pasternak	514	282	9/30/82
	DB	4	6	6	1	4	9	2	4/28/87	Lewis, et. al.	514	282	11/21/85
	DC	4	7	6	9	3	7	2	9/6/88	Kreek, et. al.	514	282	6/18/86
	DD	4	7	8	5	0	0	0	11/15/88	Kreek, et. al.	514	282	11/16/87
	DE	4	9	3	5	4	2	8	6/19/90	Lewis	514	282	11/25/88
	DF	5	1	4	9	5	3	8	9/22/92	Granger, et. al.	424	449	6/4/91
	DG	5	3	1	6	7	5	9	5/31/94	Rose, et. al.	424	10	3/23/92
	DH	5	3	2	1	0	1	2	6/14/94	Mayer, et. al.	514	25	4/6/93
	DI	5	3	5	2	6	8	0	10/4/94	Portoghese, et. al.	514	279	7/15/92
	DJ	5	3	5	6	9	0	0	10/18/94	Bihari, et. al.	514	282	5/10/93
<i>DM</i>	DK	5	3	7	6	6	6	2	12/27/94	Ockert	514	282	12/8/93

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
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	DM													
	DN													
	DO													
	DP													

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

<i>DR</i>	DR	Weinhold, LL, et. al., Buprenorphine Alone and in Combination with Naltrexone in Non-Dependent Humans, Drug and Alcohol Dependence 1992; 30:263-274.
<i>DS</i>	DS	Mendelson J., et. al., Buprenorphine and Naloxone Interactions in Opiate-Dependent Volunteers, Clin. Phar. Ther. 1996; 60:105-114.
<i>DT</i>	DT	Physician's Desk Reference 48th ed., 1994; 2120-2121, Montvale, NJ.

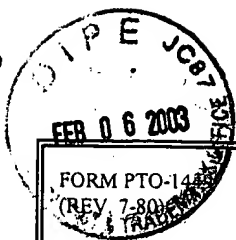
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Robert F. KAIKO

DATE CONSIDERED

4-29-03

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-144
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:
200.1102CIP

SERIAL NO.: 09/503,020

LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): Robert F. KAIKO, Robert D. COLUCCI

FILING DATE: February 11,
2000

GROUP: 1615

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
<i>Th</i>	EA	5	4	2	6	1	1	2	6/20/95	Zagon, et. al.	514	282	2/23/93
	EB	5	4	8	6	3	6	2	1/23/96	Kitchell, et. al.	424	426	10/21/93
	EC	5	4	7	2	9	4	3	12/5/95	Crain, et. al.	514	12	7/27/93
	ED	5	5	0	2	0	5	8	3/26/96	Mayer, et. al.	514	289	5/19/94
	EE	5	5	1	2	5	7	8	4/30/96	Crain, et. al.	514	282	7/19/94
	EF	5	5	1	4	6	8	0	5/7/96	Weber, et. al.	514	249	11/5/93
	EG	5	5	5	6	8	3	8	9/17/96	Mayer, et. al.	514	25	5/19/94
	EH	5	5	7	4	0	5	2	11/12/96	Rose, et. al.	514	343	4/29/94
	EI	4	8	0	3	2	0	8	2/7/89	Pasternak	514	282	10/11/85
	EJ	4	8	7	3	0	7	6	10/10/89	Fishman, et. al.	424	10	4/5/89
<i>Th</i>	EK	5	5	8	0	8	7	6	12/3/96	Crain, et. al.	514	282	11/3/95

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	EL													
	EM													
	EN													
	EO													
	EP													

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

<i>Th</i>	ER	Crain, et. al., "Ultra-low concentrations of naloxone selectively antagonize excitory effects of morphine on sensory neurons, thereby increasing its antinociceptive potency and attenuating tolerance/dependence during chronic cotreatment", Proc. Natl. Acad. Sci. USA, 1995; Vol. 92, 10540-10544.
	ES	Shen, et. al., "Ultra-low doses of naltrexone or etorphine increase morphine's antinociceptive potency and attenuate tolerance/dependence in mice", Brain Research, 757:176-190 (1997).
	ET	Holmes, et. al., Anesth. Analg. 77:1166-73 (1993).

EXAMINER

Robert D. Colucci

DATE CONSIDERED

4-29-03

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Sheet 6 of 9

FORM 1449
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:
200.1102CIP

SERIAL NO.: 09/503,020

LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): Robert F. KAIKO, Robert D. COLUCCI

FILING DATE: February 11,
2000

GROUP: 1615

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
<i>Tw</i>	FA	4	4	0	1	6	7	2	8/30/83	Portoghese, et. al	424	260	10/13/81
	FB	4	7	3	0	0	4	8	3/8/88	Portoghese, et. al	546	045	12/12/85
	FC	4	8	0	6	5	5	8	2/21/89	Wuest, et. al	514	381	9/20/85
	FD	5	4	5	7	2	0	8	10/10/95	Portoghese, et. al	546	035	6/21/93
	FE	5	5	7	8	7	2	5	11/26/96	Portoghese, et. al	546	035	1/30/95
	FF	4	7	6	0	0	6	9	7/26/88	Rzeszotarski, et. al.	514	282	9/23/85
	FG	5	5	3	4	4	9	2	7/9/96	Aston, et. al.	514	608	1/3/95
	FH	5	5	0	2	0	5	8	3/26/96	Mayer, et. al.	514	289	5/19/94
	FI	5	3	5	2	6	8	3	10/4/94	Mayer, et. al.	514	289	3/5/93
	FJ	4	8	8	9	8	6	0	12/26/89	Rzeszotarski, et. al.	514	282	4/6/87
<i>TW</i>	FK	5	0	7	5	3	4	1	12/24/91	Mendelson, et. al	514	282	12/1/89

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	FL													
	FM													
	FN													
	FO													
	FP													

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

<i>Tw</i>	FR	Miaskowski, et. al., Brain Research 596:41-45 (1992).
	FS	Vaccarino, et. al., Pain 36:103-109 (1989).
	FT	Cappel, et. al., Pharmacology Biochemistry & Behavior, Vol. 34, pp. 425-427 (1989).

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DATE CONSIDERED

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Sheet 7 of 9

FORM PTO-449
(REV. 7-80)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.:
200.1102CIP

SERIAL NO.: 09/503,020

LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): Robert F. KAIKO, Robert D. COLUCCI

FILING DATE: February 11,
2000

GROUP: 1615

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
TW	GA	5 3 1 7 0 2 2	5/31/94	Borsodi, et. al.	514	282	2/3/92
	GB	4 8 0 6 5 4 3	2/21/89	Choi	514	464	11/25/86
	GC	4 8 0 6 3 4 1	2/21/89	Chien, et. al.	424	448	9/3/86
	GD	4 8 8 2 3 3 5	11/21/89	Sinclair	514	282	6/13/88
	GE	5 0 8 6 0 5 8	2/4/92	Sinclair, et. al.	514	282	6/4/90
	GF	4 4 5 1 4 7 0	5/24/84	Ganti	424	260	7/6/82
	GG	5 0 9 6 7 1 5	3/17/92	Sinclair	424	449	11/20/89
	GH	5 2 2 5 4 4 0	7/6/93	London, et. al.	514	535	9/13/91
	GI	5 2 5 6 6 6 9	10/26/93	Askanazi, et. al.	514	282	8/7/92
TW	GJ	3 3 3 2 9 5 0	6/25/67	Blumberg, et. al.	260	285	12/6/66
	GK						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	GL							
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OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

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4-29-03

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Sheet 8 of 9

FORM PTO 449
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:
200.1102CIP

SERIAL NO.: 09/503,020

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APPLICANT(S): Robert F. KAIKO, Robert D. COLUCCI

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2000

GROUP: 1615

U.S. PATENT DOCUMENTS

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<i>TH</i>	HA	5	2	3	6	7	1	4	08/17/93	Lee et al.	424	449	Nov. 1, 1988
	HB	5	6	3	3	2	5	9	05/27/97	Qin et al.	514	282	Feb. 13, 1995
	HC	5	8	6	6	1	6	4	02/02/99	Kuczynski et al.	424	472	Mar. 12, 1997
	HD	5	8	5	8	0	1	7	01/12/99	Demopoulos et al.	604	890.1	Jun. 26, 1996
	HE	5	8	6	0	9	5	0	01/19/99	Demopoulos et al.	604	49	Jun. 26, 1999
	HF	5	8	8	0	1	3	2	03/09/99	Hill	514	282	Dec. 15, 1995
	HG	4	1	7	6	1	8	6	11/27/79	Goldberg	424	260	July 28, 1978
	HH	4	7	1	9	2	1	5	01/12/88	Goldberg	514	282	March 7, 1986
	HI	4	8	6	1	7	8	1	08/29/89	Goldberg	514	282	September 3, 1987
	HJ	5	1	0	2	8	8	7	04/07/92	Goldberg	514	282	June 15, 1990
<i>TH</i>	HK	5	9	7	2	9	5	4	10/26/99	Foss	514	282	November 3, 1997

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

<i>TH</i>	HL	Chih-Cheng Chien, Neuroscience Letters 190 (1995) 137-139
	HM	Translation of previously submitted German patent application DE 43 25 465
	HN	Walsh et al., Effects of naltrexone on response to intravenous cocaine, hydromorphone and their combination in humans (1996).
	HO	Yuan et al., Drug and Alcohol Dependence 52 (1998) 161-165
	HP	Yuan et al., Clinical Trials and Therapeutics, 61 (April 1997) 467-475.
	HQ	Foss et al., J Clin Pharmacol 33 (1993) 747-751.
<i>TH</i>	HR	Abstract, Cancer Chemother Pharmacol 1998; 42(4):287-91

EXAMINER

DATE CONSIDERED

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P.O. 1449
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:
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SERIAL NO.: 09/503,020

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APPLICANT(S): Robert F. KAIKO, Robert D. COLUCCI

FILING DATE: February 11,
2000

GROUP: 1615

U.S. PATENT DOCUMENTS

*EXAMINE R INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
<i>TD</i>	IA	5	9	9	8	4	3	4	12/07/99	Mitch, et al.	514	305	Dec. 5, 1996
	IB	5	9	6	8	5	4	7	10/19/99	Reder, et al.	424	449	Sept. 29, 1997
	IC	4	8	6	1	5	9	8	8/29/89	Oshlack	424	468	Jul. 18, 1986
	ID	5	2	7	3	7	6	0	12/28/93	Oshlack, et al.	424	480	Dec. 24, 1991
	IE	5	9	4	2	2	4	1	8/24/99	Chasin, et al.	424	426	Jun. 7, 1996
<i>TD</i>	IF	6	2	2	8	8	6	3	5/08/01	Palermo, et al.	514	282	Dec. 22, 1998
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FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
<i>TD</i>	IK	0	2	0	5	2	8	2	12/17/86	EP (A2)	A61K	9/22		

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

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FORM PTO-1449
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.: 200.1102CP2

SERIAL NO.: 09/992,936

LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): Robert F. KAIKO, et al.

FILING DATE: November 5, 2001

GROUP: 1615

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA						
	AB						
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FOREIGN PATENT DOCUMENTS

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							YES	NO
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<i>TH</i>	AM	Hanson. Analgesic, antipyretic and anti-inflammatory drugs. In: Remington's Science and Practice of Pharmacy, vol. 2: 1207 (1995).
	AN	
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APPLICANT(S): Robert F. KAIKO, et al.

FILING DATE: November 5, 2001

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AM	Vicodin®. Physicians' Desk Reference 48 th ed., 1994; pp 1143-1145.
AN	Lorcet®. Physicians' Desk Reference 48 th ed., 1994; pp 2388-2390.
AO	Lortab®. Physicians' Desk Reference 48 th ed., 1994; pp 2498-2500.
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